R E M A R K S

Objection to Specification in the October 21, 2008 Office Action

The disclosure was objected to on page 2 of the October 21, 2008 Office Action for the reason that the term "antimicrobial" was not spelled correctly on page 6 of the specification. The CORRECTED ENGLISH-LANGUAGE TRANSLATION OF INTERNATIONAL APPLICATION OF PCT/JP03/01897 was amended hereinabove to correct the spelling of "antimicrobial."

Withdrawal of the objection to the specification is respectfully requested.

Claim Amendments

In reply to item no. 3 of the February 12, 2009 ADVISORY ACTION, claim 8 was amended hereinabove to replace the terminology of "consisting essentially of" with the originally claimed terminology of "comprising."

Claim 12 was amended to make a minor editorial revision.

Rejection Under 35 USC 112, First Paragraph
in the October 21, 2008 Office Action

Claims 6, 8 to 10, 12 and 16 were rejected under 35 USC 112, first paragraph, for alleged lack of enablement for the reasons set forth on pages 3 to 8 of the October 21, 2008 Office Action.

The position was taken in the Office Action that the present specification does not reasonably provide enablement for the treatment of age-related macular degeneration, retinitis pigmentosa, central retinal vein occlusion or central retinal artery occlusion. On the other hand, it was acknowledged in the October 21, 2008 Office Action that the present specification reasonably provides enablement for treatment of uveitis, cytomegalovirus retinitis, diabetic retinopathy, proliferative vitreoretinopathy and retinal detachment, and that betamethasone, dexamethasone, triamcinolone and prednisolone may be useful for treating these diseases (or conditions).

The present claims do not recite the terminology of "preventing." The present claims recite only the diseases of the posterior segment that the Examiner indicated were enabled, namely uveitis, cytomegalovirus retinitis, diabetic retinopathy,

proliferative vitreoretinopathy, and retinal detachment, as well as age-related macular degeneration.

It is respectfully submitted that the terminology of age-related macular degeneration that is recited in applicants' present claims is enabled for the following reasons.

It has been reported that an intravitreal injection of triamcinolone (a drug disclosed in the present specification as a therapeutic agent) improves visual acuity and fundus findings in exudative macular degeneration (see the copy of Retina, 20(3), 244-250 (2000) that was enclosed with the AMENDMENT UNDER 37 CFR 1.116 filed January 16, 2009). It has also been reported that an intravitreal injection of triamcinolone may be an acceptable treatment for subfoveal recurrent neovascularisation after laser photocoagulation for exudative macular degeneration (see the copy of Br. J. Ophthalmol., 86(5), 527-529 (2002) that was enclosed with the AMENDMENT UNDER 37 CFR 1.116 filed January 16, 2009). It is respectfully submitted that in view of the foregoing facts and having the benefit of the disclosure in applicants'

specification, the treatment of age-related macular degeneration according to applicants' present claims is enabled.

Withdrawal of the 35 USC 112, first paragraph rejection is thus respectfully requested.

Anticipation Rejections Under 35 USC 102
in the October 21, 2008 Office Action

Claims 1, 6 and 7 were rejected as being anticipated by Gwon et al. (USP 5,300,114) for the reasons stated on pages 8 to 9 of the October 21, 2008 Office Action.

In view of the above cancellation of claims 1, 6 and 7, withdrawn of this rejection is respectfully requested.

Claims 1, 2, 4, 6 to 8, 10, 12, 14, 16 and 17 were rejected under 35 USC 102 as being anticipated by Peyman (USP 6,395,294) for the reasons indicated on pages 9 to 14 of the October 21, 2008 Office Action.

It is noted that claims 3 and 9 were not included in this rejection.

Since the features of claims 3 and 9 ("a particle diameter of the fine particles is 50 nm to 150 μm") is presently recited

in applicants' claim 8 and since claims 10 and 12 depend on claim 8, withdrawal of this anticipation rejection is respectfully requested

Obviousness Rejection Under 35 USC 103
in the October 21, 2008 Office Action

Claims 3, 9 and 13 were rejected under 35 USC 103 as being unpatentable (obvious) over Peyman (USP 6,395,294) in view of Ogura et al. (JP 2000-247871) for the reasons set forth on pages 10 to 11 of the October 21, 2008 Office Action.

Claim 3 has been canceled.

Peyman discloses merely a surgical method to alleviate a structural disorder of an eye. Peyman's method requires not only injecting a drug into the eye, but also surgically correcting the disorder by removing the vitreous (see claim 1 of Peyman). In contrast thereto, the presently claimed invention relates to a method of treating an ocular disorder by carrying out only a subconjunctival administration of an injection solution comprising fine particles containing a drug (see applicants' present claim 8).

It was pointed out in the October 21, 2008 Office Action that Peyman discloses a particle size of less than 50 μm, and Ogura et al. teach a drug release control system for treating various diseases of a retina or vitreous body, wherein the drug has a particle diameter in the range of 50 to 200 nm. Therefore, it was concluded in the October 21, 2008 Office Action that it would have been obvious to one of ordinary skill in the art to modify the particle size of the drug, as desired, in order to provide a controlled release of the drug in the retina (drug emission control over a long period of time).

However, although Peyman discloses that the preferable size of vitreous delineating agents (e.g., corticosteroid) in his surgical method is less than 50 μm, Peyman does not disclose or suggest which particle size is preferable to enable the drug concentration in a retina-choroid to be sustained by a subconjunctival administration of an injection comprising fine particles containing a drug, as recited in applicants' claim 8. Therefore, it is respectfully submitted that Peyman would not lead one of ordinary skill in the art to adjust the particle size

of a drug to 50 nm to 150 μm, and such person of ordinary skill in the art would not arrive at the presently claimed invention.

Ogura et al. disclose that the particle diameter must be 50 to 200 nm in order to provide a controlled release of a drug in the retina. In other words, Ogura et al. teach that the drug-containing fine particles whose diameter is more than 200 nm are unfavorable to provide a controlled release of the drug in the retina. In contrast thereto, the particle diameter of the fine particles in the presently claimed invention is 50 nm to 150 μm, and preferably 200 nm to 75 μm (see page 5, lines 17 to 23 of the present specification). This means that in the presently claimed invention most of fine particles containing a drug have a particle size of more than 200 nm. Accordingly, Ogura et al. thus teach away from the presently claimed invention.

Thus, in Peyman and Ogura et al., there is no teaching or suggestion as to how to arrive at a drug concentration in a retina-choroid to be sustained by a subconjunctival administration, as recited in applicants' present claims.

The present inventors discovered after intensive study that the subconjunctival administration of fine particles containing a drug and enabling the drug concentration in the retina-choroid to be sustained is advantageous for treating a disease of a posterior segment of an eye. It is respectfully submitted that these findings constitute a showing of unexpected results. Moreover, the present invention is also clinically significant since the presently claimed invention reduces the burden of patients by avoiding a vitreous injection and frequent subconjunctival injections.

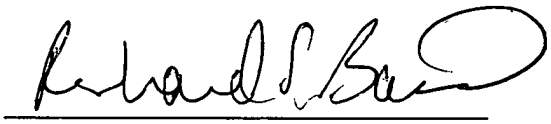
Accordingly, it is respectfully submitted that it would not be obvious for one of ordinary skill in the art to modify the particle size of the drug, as desired, in order to provide a controlled release of a drug in the retina.

Withdrawal of the 35 USC 103 rejection is therefore respectfully requested.

Reconsideration is requested. Allowance is solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,



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